IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	
Plaintiffs,	)	C.A. No. 18-823-CFC-JLH
v.	)	[redacted]
EAGLE PHARMACEUTICALS INC.,	)	
Defendant.	)	

LETTER TO THE HONORABLE COLM F. CONNOLLY
BINDU A. PALAPURA, ESQUIRE

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Dated: October 28, 2020
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October 28, 2020

VIA ELECTRONIC FILING
The Honorable Colm F. Connolly
United States District Judge
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801

[redacted]

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823-CFC-JLH

Dear Judge Connolly:

I write on behalf of Eagle Pharmaceuticals in response to Par's October 26 letter submitted in advance of today's Status Conference (D.I. 210). Eagle proposed that the parties request a status conference in order to apprise the Court of the current landscape, including the possibility of a launch-at-risk scenario and/or injunctive relief that Par might seek. The parties had discussed possible joint proposals for how we could proceed, but did not reach agreement.

[redacted]

The salient issue before the Court is when to schedule trial and/or preliminary injunction proceedings, so that the Court and parties can proceed in an orderly fashion now that the 30-month stay of final approval of Eagle's ANDA has expired. [redacted] Since FDA has granted Eagle's ANDA "priority review" [redacted] " FDA could approve at any time, even before the end of this year. Eagle has invested heavily in the development of this product, which is important to Eagle's business. [redacted]

That means these issues could come to a head at any time. Eagle thus believes it is in the interests of the Court and parties to schedule trial, and/or prepare for and schedule proceedings for injunctive relief, sooner rather than later, if possible. Otherwise, the parties may come to the Court on an even more urgent or emergency basis, which could be particularly unideal given the complexities of the Court's schedule due to the pandemic. [redacted] having had injunction proceedings or a trial already would provide more certainty and [redacted] Indeed, one goal of the Hatch-Waxman framework is to get to trial and decision before a launch, which is why litigation runs in parallel to FDA proceedings and trials often occur before tentative approval.

As for the merits of Par's assertion [redacted] (D.I. 210), it misses the mark. Par correctly acknowledges—as it has to—that FDA has granted "priority review" to Eagle's ANDA. Par Ex. I. Par states that priority review [redacted] D.I 210, Attachment at 2. [redacted] Under FDA's Manual of Policy and Procedures, an ANDA granted priority review may receive ***either*** a shorter goal date (***if*** the submission has not yet been assigned a goal date), ***or*** expedited review. FDA MaPP 5240.3 Rev. 5 at 3. Here, [redacted] Par Ex. I.

Par's argument that [redacted]" (D.I. 210), is wholly speculative. [redacted]. Likewise, [redacted] (D.I. 210, Attachment at 2), deserves no serious consideration. Eagle [redacted] Par Ex. G at 6–7. [redacted] And in any event, since even Par acknowledges [redacted] scheduling trial and/or injunction proceedings now would allow for an orderly trial or hearing, and briefing, before Eagle's launch, much like the time between the original May 2020 trial date and the October 2020 expiry of the 30-month stay, which was set for that very reason.

We look forward to discussing these issues during the upcoming Status Conference.

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

BAP:nmt/6915254/45185
cc: Counsel of Record (via electronic mail)